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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,888	07/17/2003	Robert Gurny	4-20437D	7666

1095 7590 03/16/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,888	GURNY ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 32 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 2-26-07 is acknowledged.

Claims included in the prosecution are 1, 32 and 34-38.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1,32 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allemann et al (international Journal of Pharmacology, 1992) of record in combination with Kelm (5,651983).

Allemann et al disclose a process of preparation of polymeric nanodispersions containing water-soluble polymer (polyvinyl alcohol) and Eudragit S (anionic polymer which is soluble from pH 7 upwards) or ethyl acetate (abstract and page 248). What is lacking in Allemann is the teaching of the use of these nanospheres for encapsulating water insoluble drugs. However, on page 253 Allemann teaches that these nanospheres are for sustained release dosage forms and therefore, it would have been prima facie obvious to one of ordinary skill in the art to use Allemann's nanosphere dispersions for the water insoluble drugs with a reasonable expectation of success. What is lacking in Allemann is the teaching of polyvinyl phthalate instead of Eudragit.

Kelm while disclosing enterically coated powdered suspensions of bisacodyl teaches that either Eudragit or polyvinyl acetate phthalate or other enteric polymers could be used to coat bisacodyl (examples and claim 7).

It would have been obvious to one of ordinary skill in the art to use polyvinyl acetate phthalate instead of Eudragit in the compositions of Allemann with a reasonable expectation of success since Kelm teaches that either Eudragit or polyvinyl acetate phthalate could be used to coat powdery suspensions for colonic delivery. Although Allemann does not disclose instant compound in claim 38, it would have been obvious to one of ordinary skill in the art to encapsulate any compound in the dispersions of Allemann with a reasonable expectation of success from the guidance provided since the principle is the same.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that on page 253 Allemann states that the results with the biocompatible poly (dl-lactic acid) should permit the use of this process for injectable sustained release dosage forms and for drug targeting and therefore, the only route of administration specifically mentioned is a parenteral route whereas the present invention focuses on an oral route of administration. The examiner disagrees with this interpretation of reference's teachings. Allemann's statements of injectable dosage form appear to refer to preparations only when poly (dl-lactic acid) is used. In the first part of 'conclusions', Allemann refers to both PLA and Eudragit, which is used in oral preparations as also evident from Kelm. Applicant's arguments that Kelm specifically states that the dosage forms of the present invention are to be distinguished from

controlled release compositions which slowly release a drug active over an extended period of time and therefore, this statement would discourage a combination of references is not persuasive since the combination is made for the teachings of the use of Eudragit and polyvinyl acetate phthalate and this teaching would be the same irrespective of the nature of the release of the active agent, that is, whether it is a sustained release or immediate release composition. Similar is the case with applicant's arguments regarding the solubility of bisacodyl taught by Kelm. That is, the release of an agent in the intestines because of the coating by an enteric coating (polyvinyl acetate phthalate) would be the same regardless of whether the active agent is soluble or insoluble.

2. Claims 1, 32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allemann et al (international Journal of Pharmacology, 1992) of record in combination with Kawata (4,343,789), Kantor (4,895,725) by themselves or in combination, further in view of Kelm.

Allemann et al disclose a process of preparation of polymeric nanodispersions containing water-soluble polymer (polyvinyl alcohol) and Eudragit S (anionic polymer which is soluble from pH 7 upwards) or ethyl acetate (abstract and page 248). What is lacking in Allemann is the teaching of the use of these nanospheres for encapsulating water insoluble drugs. However, on page 253 Allemann teaches that these nanospheres are for sustained release dosage forms and therefore, it would have been

prima facie obvious to one of ordinary skill in the art to use Allemann's nanosphere dispersions for the water insoluble drugs with a reasonable expectation of success.

As pointed out in the earlier action, Kawata et al disclose fine powders of active agents of low solubility coated with various copolymers of methacrylic acid and methacrylic esters or hydroxypropylmethyl cellulose phthalates. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized. (Abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims).

Kantor teaches that lipophilic compounds such as fish oils can be delivered orally by using enterically coated capsules. The lower limit of the capsules is 100 nm. The enteric polymers are claimed cellulose acetate phthalate and cellulose acetate trimellitate (Examples and claims 4 and 5).

What is lacking in Kawata or Kantor is the teaching of polyvinyl acetate phthalate as the enteric material, which is resistant to gastric juices and soluble in intestinal juices. Assuming that Allemann's drugs are not water insoluble, one of ordinary skill in the art would be motivated to use Allemann et al's nanodispersions for the delivery of water insoluble drugs with a reasonable expectation of success since Kawata shows the feasibility of enteric delivery of water insoluble drugs using enteric formulations containing water insoluble drugs. One of ordinary skill in the art would be motivated to use the formulations of Allemann and containing water insoluble drugs orally since Kantor teaches that suspensions of enterically coated nanocapsules can be administered orally. The use polyvinyl acetate phthalate instead of Eudragit in the compositions of Allemann with a reasonable expectation of success would have been

obvious to one of ordinary skill in the art since Kelm teaches that either Eudragit or polyvinyl acetate phthalate could be used to coat powdery suspensions for colonic delivery. Although Allemann does not disclose instant compound in claim 38, it would have been obvious to one of ordinary skill in the art to encapsulate any compound in the dispersions of Allemann with a reasonable expectation of success from the guidance provided since the principle is the same.

Applicant's arguments with regard to Allemann, and Kelm have been discussed above. Applicant provides no specific arguments with regard to Kawata and Kantor. Therefore, the rejection is maintained.

3. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allemann et al (international Journal of Pharmacology, 1992) of record in combination with Kelm (5,651983) OR Allemann et al (international Journal of Pharmacology, 1992) of record in combination with Kawata (4,343,789), Kantor (4,895,725) by themselves or in combination, further in view of Kelm as set forth above, further in view of EP 618 222 cited on page 5 of the specification.

The teachings of Allemann, Kelm Kawata, and Kantor have been discussed above. What is lacking in these references is the teaching of instant compound.

EP discloses that the claimed compound is art known. It would have been obvious to one of ordinary skill in the art to encapsulate any compound including the compound known in the art as taught by EP in the dispersions of Allemann with a reasonable expectation of success from the guidance provided since the principle is the same.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK